NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WYETH and CORDIS CORPORATION, Plaintiffs, v. ABBOTT LABORATORIES and ABBOT CARDIOVASCULAR SYSTEMS, INC.; BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Defendants.	:	Civil Action No. 08-0230 (JAP) **OPINION**

PISANO, District Judge.

Presently before the Court is Defendants' motion to dismiss Plaintiffs' Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(1). Plaintiffs oppose the motion.

The Court has jurisdiction to hear this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Having considered all arguments presented, the Court denies Defendants' motion to dismiss.

I. Factual Background

Plaintiff, Wyeth ("Wyeth") is a Delaware corporation with a place of business in Madison, New Jersey. Wyeth is engaged in the development of pharmaceutical drugs and treatments across a range of therapeutic areas. Plaintiff, Cordis Corporation ("Cordis") is a

Florida corporation with a principal place of business in Warren, New Jersey. Cordis also has facilities in Clinton, New Jersey and develops invasive treatments for vascular disease.

Defendant, Abbott Laboratories is an Illinois corporation with a principal place of business in Illinois. Defendant, Abbot Cardiovascular Systems, Inc. is a corporation organized under the laws of California and has a principal place of business in California. Abbott Cardiovascular Systems, Inc. is a subsidiary of Abbott Laboratories. Abbott Laboratories and Abbott Cardiovascular Systems, Inc. will be collectively referred to herein as "Abbott." Abbott is registered to do business in New Jersey and has facilities located throughout this State.

Defendant, Boston Scientific Corporation is a Delaware corporation with a principal place of business in Massachusetts. Defendant, Boston Scientific Scimed, Inc. is a Minnesota corporation with its principal place of business in Minnesota. Boston Scientific Scimed, Inc. is a subsidiary of Boston Scientific Corporation. Herein, Boston Scientific Scimed, Inc. and Boston Scientific Corporation will be referred to as "BSC." BSC regularly transacts business within New Jersey such as the sale and distribution of medical devices, including vascular devices.

Wyeth is the owner of several patents. On May 12, 1994, the United States Patent and Trademark Office ("USPTO") issued United States Patent No. 5,516,781, entitled "Method of Treating Restenosis with Rapamycin" ("'781 Patent"). On October 8, 1996, the USPTO issued United States Patent No. 5,563,146, entitled "Method of Treating Hyperproliferative Vascular Disease ("'146 Patent"). On September 9, 1997, the USPTO issued United States Patent No. 5,665,728, entitled "Method of Treating Hyperproliferative Vascular Disease ("'728 Patent"). Wyeth has granted Cordis exclusive license to practice each of those patents in the field of percutaneous transluminal procedures in humans.

Currently, Cordis manufactures a drug-eluting coronary stent called the Cypher stent, which it markets and sells in the United States and abroad. Abbott also manufactures a drug-eluting coronary stent named Xience Everolimus Eluting Coronary Stent System ("Xience V stent"). Although the Xience V stent is manufactured in the United States, it is not yet sold here; however, it launched for sale in Europe and Asia in 2006. Abbott has publicly announced that it has sought approval from the FDA to sell the Xience V stent in the United States and that, assuming it gets regulatory approval, Abbott intends on launching the Xience V stent in the first half of 2008.

Pursuant to an agreement between BSC and Abbott, BSC is presently selling the Promus stent, a private label version of Xience V stent, in Europe and other countries. The Promus stent is manufactured for BSC by Abbott in the United States and in October 2006, it received CE Mark approval, which allows BSC to distribute the Promus stent in Europe. BSC has publicly stated that it has sought approval from the FDA to sell the Promus stent in the United States for use by physicians in coronary angioplasty procedures. On November 29, 2007, an advisory committee to the FDA voted to recommend approval of Abbott's Xience V stent. Because the Xience V stent is the same as the Promus stent, BSC has also publicly stated that, assuming they receive FDA approval, they intend to launch the Promus stent for sale in the United States.

II. Procedural History

On January 1, 2008, Plaintiffs filed a three count Complaint against Defendants. In their Complaint, Plaintiffs alleged infringement by Abbott of the '781 Patent (Count One), infringement of the '146 Patent (Count Two), and infringement of the '728 Patent (Count Three).

Plaintiffs then filed an Amended Complaint on February 1, 2008, which incorporated the counts for infringement and included three additional counts for declaratory judgment against BSC for the infringement of the '781, '146, and '728 Patents (Counts Four-Six).

Plaintiffs assert that Abbott, by making and/or using the Xience V stent in the United States for sale in Europe and Asia and making and/or selling the Xience V stent to BSC for resale under the Promus name, is "directly infringing, contributorily infringing, and/or inducing infringement of [their patents] in violation of 35 U.S.C. § 271." Pl. Am. Compl. ¶¶ 23, 26, 29. Plaintiffs also seek a declaratory judgment from the Court that finds the future sale of BSC's Promus stent infringes on Plaintiffs' patents in violation of 35 U.S.C. § 271.

On March 17, 2008, Defendants filed the present motion to dismiss Plaintiffs' Amended Complaint, which Plaintiffs oppose. The Court now decides the motion.

III. Legal Discussion

a. Standard of Review

Under Fed. R. Civ. P. 12(b)(1) a party may move for dismissal of a case based on lack of subject matter jurisdiction. FED. R. CIV. P. 12(b)(1). A plaintiff bears the burden of proving that subject matter jurisdiction properly exists in the federal court. *Mortensen v. First Fed. Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977). When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Id.*

Moreover, "[w]hen a motion to dismiss is based on a lack of subject matter jurisdiction pursuant to Rule 12(b)(1), as well as other Rule 12(b) defenses, the Court should consider the Rule 12(b)(1) challenge first because, if it must dismiss the complaint for lack of subject matter jurisdiction, the accompanying defenses become moot and need not be addressed." *Pashun v. Modero*, No. 92-3620, 1993 U.S. Dist. LEXIS 7147, at *5 (D.N.J. May 26, 1993).

b. Legal Analysis

"[T]he first and fundamental question" that a federal court must address in each case "is that of jurisdiction." *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998). Federal district courts have original jurisdiction over all civil actions arising under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1331. Federal district courts also have original jurisdiction over any civil action arising under any act of Congress relating to patents. 28 U.S.C. § 1338(a).

The Declaratory Judgment Act provides that "[i]n a case of actual controversy...any court of the United States...may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Thus, in order for a court to exercise jurisdiction over a declaratory judgment action, there must be an actual and adverse controversy. "'The question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

In other words, the *MedImmune* "all the circumstances" test must demonstrate that a justiciable Article III controversy exists. The party seeking declaratory judgment jurisdiction must "satisfy Article III, which includes standing and ripeness, by showing under 'all the circumstances' an actual or imminent injury caused by the defendant that can be redressed by judicial relief and that is of 'sufficient immediacy and reality to warrant the issuance of a declaratory judgement.'" *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1338 (Fed. Cir. 2007) (quoting *MedImmune,* 127 S. Ct. at 771). Further, "the burden is on the party claiming declaratory judgment jurisdiction to establish that jurisdiction existed at the time the complaint was filed and if it continued since." *Benitec Astl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

Under Article III of the Constitution, the jurisdiction of federal courts extends only to the resolution of "cases" and "controversies." U.S. CONST. ART. III § 2. To demonstrate a case or controversy, a plaintiff must establish standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) ("Though some of its elements express merely prudential considerations that are part of judicial self-government, the core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III."). The "irreducible constitutional minimum of standing" requires: (1) "the plaintiff must have suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical;" (2) "there must be a causal connection between the injury and the conduct complained of–the injury has to be fairly...trace[able] to the challenged action of the defendant, and not...th[e] result [of] the independent action of some third party not before the court;" and (3) "it must be likely, as opposed to merely speculative, that the injury will be

redressed by a favorable decision." *Id.* at 560-61 (internal citations and quotations omitted) (alterations in *Lujan*).

In addition to standing, Article III justiciability requires that the case be ripe for judicial review. Ripeness focuses on whether the conduct of the defendant harmed, is harming, or will harm legal interests of the plaintiff, and the question presented involves a question of law, which postponement of a decision would cause a substantial hardship on the party seeking the declaratory judgment. *See Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). Thus, in order to have a justiciable controversy within Article III, there must be an "actual controversy;" a dispute that is "definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit specific relief through a decree of a conclusive character." *MedImmune*, 127 S. Ct. at 771.

Typically, declaratory judgment actions in patent cases are brought by "potential infringers against patentees seeking a declaration [by the court] of noninfringement or invalidity or both." *Lang. v. Pac. Marine & Supply Co.*, 895 F.2d 761, 763 (Fed. Cir. 1990). *See also SanDisk Corp. v. STMicroelectronics NV*, 480 F.3d 1372, 1381 (Fed. Cir. 2007) ("where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights"). The Lang court, however, acknowledged that "declarations of infringement sought by patentees against parties who will allegedly infringe in the future have been less frequently requested, but have nevertheless been allowed to proceed." *Id.* at 763.

Plaintiffs seek a declaration of infringement against BSC because BSC intends to market and sell its Promus stent immediately upon approval from the FDA, which Plaintiffs contend would infringe on their patents and product, particularly its Cypher stent. Defendants argue that Plaintiffs are not entitled to a declaratory judgment because no actual controversy exists that gives this Court jurisdiction. The Court concludes that, at the time Plaintiffs' Amended Complaint was filed, an actual controversy under the Declaratory Judgement Act did and continues to exist.

The Court finds that an actual controversy does exist because of the time frame within which Defendants will market their products once they obtain FDA approval. Currently, the Promus stent is already being marketed and sold in Europe and Asia. Although the FDA has yet to approve Defendants' application and the product has not yet been marketed in the United States, Plaintiffs have demonstrated that Defendants are in the process of launching a product that would be subject to an infringement action under 35 U.S.C. § 271. BSC's attorney, Todd Messal, stated in a declaration submitted to the Delaware district court, in connection with the actions proceeding there, that "BSC has been selling the [Promus] stent in Europe since January 2007, and expects to be able to sell it in the United States in the first or second quarter of 2008." Messal Decl. ¶¶ 6-8.

Moreover, in the Form 10-Q Report that BSC filed with the Securities and Exchange Commission on November 7, 2007, BSC reported that "in June, Abbott submitted the final module of a pre-market approval (PMA) application to the FDA seeking approval in the U.S. for both [Xience] and [Promus] stent systems. An FDA advisory panel meeting is scheduled for November 29, 2007 to review Abbott's PMA submission. Upon approval, which Abbott is

expecting in the first half of 2008, we plan to launch the [Promus] stent system in the U.S. simultaneously with Abbott's launch of [Xience]." Spanbauer Decl., Ex. B at 37.

It is irrelevant, as BSC highlights, that patentees typically do not have recourse to the declaratory judgment statutes. The time frame provided by both Mr. Messal and BSC's Form 10-Q creates a "sufficient immediacy and reality [of a conflict due to adverse legal interests] to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (citations and quotation marks omitted). Unlike the defendant in *Eisai Co., Ltd. v. Mutual Pharmaceutical Co., Inc.*, No. 06-3613, 2007 U.S. Dist. LEXIS 93585 (Dec. 20, 2007), Abbott and BSC have clearly made preparations for launch of their stents within the next few months. The *Eisai* court found that the defendant had not only made no preparations to launch the potentially infringing product, but that the defendant had "'not made a decision to launch,'" and if the company decided to launch, it would take "'at least six months to launch the product.'" *Eisai*, 2007 U.S. Dist. LEXIS 93585 at *67 (quoting from the Foster Declaration in the case). Therefore, because the defendant's launch of the generic drug was only a mere possibility, the court dismissed the action.

Here, however, Defendants' marketing and launch of their stents post-FDA approval is a certainty. Defendants have made their intent clear. Both BSC and Abbott plan to sell their product at the earliest opportunity once they receive FDA approval. An advisory committee to the FDA has already recommended the agency grant approval of Defendants' stents. Additionally, the Promus stent is currently being sold and marketed abroad. "There is no doubt about the Defendants' plans to market [the stents] at the earliest opportunity, in the face of [Plaintiffs'] patent claims. Nor is there any question about its immediate capacity to do so upon

FDA approval." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104, 112 (D. Mass. 1998).[1] *Contra Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, No. 05-590, 2006 U.S. Dist. LEXIS 57469 (D. Del. Aug. 16, 2006) (dismissing a declaratory judgment claim for lack of sufficient reality and immediacy where the defendant's product could change based on FDA approval, FDA approval could not be predicted, and the defendant had not yet distributed any promotional or sales material about the product). Thus, Plaintiffs have presented a declaratory judgment claim of sufficient immediacy and reality so that the Court has jurisdiction.

Furthermore, the Court determines that an actual controversy exists because BSC initiated four actions, involving the Promus stent, in Delaware district court and sought a declaration that those actions *did* involve an actual case or controversy. Between May 2007 through November 2007, BSC initiated four declaratory judgment actions against Cordis and its parent corporation, Johnson & Johnson ("J&J"), in the District of Delaware.[2] Each action asked the court to declare that BSC's Promus stent did not infringe on the particular Cordis patents and that the Cordis patents in question were invalid. *See, e.g., Boston Scientific Corp. v. Johnson & Johnson*, 532 F. Supp. 2d 648 (D. Del. 2008).

In the Delaware actions, BSC asserted an actual case or controversy existed between the

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[1] The *Amgen* court, however, declined to exercise jurisdiction over the declaratory claim for a variety of reasons including the uncertainty of FDA approval, the potential alteration of the product, and subjecting the defendants to infringement litigation was contrary to the Congressional policy underlying the § 271(e)(1) exemption. Here, these reasons do not apply.

[2] BSC sued Cordis and J&J on June 1, 2007 in the District of Delaware seeking a declaratory judgment that Cordis' Wright '3286 Patent was invalid and not infringed by the Promus stent (Civ. No. 1:07-cv-00348-SLR). BSC sued Cordis, in the same court seeking the same, but for Cordis' Wright '473 Patent (Civ. No. 1:07-cv-00409-SLR) on June 22, 2007 and the Falotico '662 Patent on November 27, 2007 (Civ. No. 1:07-cv-00765-SLR).

parties to establish subject matter jurisdiction. As it does here, BSC claimed that the Promus stent would get FDA approval within the first or second quarter of 2008 and that it intended to sell the stent immediately after receiving approval. Therefore, BSC argued that it sought a declaratory judgment because it feared being sued for patent infringement by Cordis once the Promus stent received approval and was sold. The Delaware court agreed with BSC and found that an actual case or controversy existed as early as when the first action was filed in May 2007.

"It logically follows that if such an action [such as the Delaware action] creates a justiciable controversy for one party, the same action should create a justiciable declaratory judgment controversy for the opposing party." *Teva*, 482 F.3d at 1342. In *Teva*, Novartis, the defendant, held a new drug application ("NDA") and upon filing its NDA, listed five patents in the FDA's Orange Book. Teva, the plaintiff, then filed an abbreviated new drug application ("ANDA") with the FDA for a generic version of the drug and certified under paragraph IV of 21 U.S.C. § 335(j)(2)(A)(vii) that its drug did not infringe on any of Novartis' five patents or that the patents were invalid. Novartis brought suit against Teva for patent infringement on one of the five of its patents. While that action was pending, Teva filed a declaratory judgment action on the four remaining patents. Novartis moved to dismiss for lack of subject matter jurisdiction. The district court dismissed Teva's declaratory action; it found it lacked jurisdiction because Teva failed to establish a reasonable apprehension of imminent suit. The Federal Circuit reversed.

The Federal Circuit found that Teva did demonstrate an Article III controversy, reasoning that "a justiciable controversy can arise from either an actual or an imminent injury." *Id.* at 1341. The circumstances, as a whole, established a justiciable controversy for the court. Because

Teva's act of submitting an ANDA was statutorily considered infringement and Novartis would have had "an immediate justiciable controversy against Teva as soon as Teva submitted the ANDA," the court reasoned that Teva, too, had a justiciable controversy against Novartis. *Id.* at 1342.

Similar to Teva, Plaintiffs have a justiciable controversy. "A useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff." *Benitec*, 495 F.3d at 1344. *See also Md. Cas. Co.*, 312 U.S. at 273 ("It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit [the potential infringer bringing a declaratory judgment action against the patentee] are reversed; the inquiry is the same in either case."). If BSC has standing for a declaratory judgment action involving its Promus stent in Delaware, there is no reason why it should not be considered an "actual case or controversy" for purposes of standing in this action. Therefore, the Court finds that it does have jurisdiction over Plaintiffs' declaratory judgment action and Defendants motion to dismiss Plaintiffs' Amended Complaint is denied.

IV. Conclusion

For the reasons stated above, it is therefore the finding of the Court that it has jurisdiction over Plaintiffs' declaratory judgment action. Therefore, Defendants' motion to dismiss Plaintiffs' Amended Complaint is denied. An appropriate order follows.

/s/ JOEL A. PISANO
United States District Judge

Dated: May 8, 2008